

The Regulation of Online Pharmacies; The Need for a Combined Federal and State Effort

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Spring 2005

Multi-State Litigation

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I. Introduction.

The federal government has failed to adequately respond to the ever growing need for regulation of Internet commerce. This failure is no more apparent than in the online prescription industry. Online pharmacies provide Americans- who are struggling to keep up with the rise of prescription drug costs- an alternative that is cost effective, convenient, and that provides more privacy than the traditional brick and mortar pharmacies. Unfortunately, there has been a consistent rise of illegitimate online pharmacies whose emergence and regulation are inadequately handled by the current patchwork of state and federal legislation. In many instances, these pharmacies provide pharmaceuticals to consumers without the traditional face-to face physical examination by a physician; others prescribe deadly drugs by only requiring that the consumer fill out an effortless questionnaire. The perils of this type of health care are more than palpable.

Traditionally, the power to regulate pharmacies and their services has been reserved with the States. Within this context, each state's attorney general and state licensing board were the primary prosecutors against pharmacies under existing state pharmacy and consumer protection laws, and codes of professional conduct. This prosecuting power is severely undermined by their lack of territorial jurisdiction beyond their state. Under current law, to stop a national online pharmacy with sales in every state it would have to be prosecuting individually in every state. This type of hardship on the States and online pharmacy industry seems undue and unnecessary, particularly when it can be easily resolved by passing the currently proposed Federal legislation.

This comment examines and discusses the roles that the federal government, state legislatures, and state attorneys general have played in regulating the online pharmacy industry. Section one begins by relating some of the major reasons for growth in online pharmacies. This is followed by an examination of the advantages and disadvantages that online pharmacies can provide consumers; thereafter, there will be a description of the major classifications of online pharmacies.

Section two will discuss the measures taken by both the federal and state governments. This section begins by first discussing the major federal agencies involved in regulating online pharmacies, and their specific areas of jurisdiction. Additionally this section describe the actions that the U.S. Congress and individual state legislatures, state Attorneys General Offices, and the industry have taken to improve customer safety and confidence in using online pharmacies. Throughout the paper, the author gives his opinion criticizing or supporting the respective bodies of government or professional

associations and their attempt to regulate the industry. A culmination of this opinion is represented in the conclusion.

II. The Growth of the Online Pharmacies Industry

A. Changes in Health Care and FDA Policy

Increasing costs of health care and prescriptions and the growth of commerce conducted over the Internet are the most evident factors that have contributed to the continued growth of the online pharmaceutical sales industry. Many attribute industry growth to the lack of appropriate legislative measures taken by the federal and state governments to decrease or limit the skyrocketing health care costs. Additionally, consumers are realizing that the Internet provides a viable mechanism to capture actual savings in health care and prescription drugs.¹ As more Americans gain access to the Internet in their homes, their confidence in this conduit for information, communication, and shopping continues to strengthen.² A further analysis shows us other underlying reasons that have also contributed to the popularity of online pharmacies. Among these reasons are lower patient expectations from the health care system and the Food and Drug Administration's ("FDA") deregulation of prescription advertising, which has resulted in an increase of direct advertising to consumers.³

¹ See: United States General Accounting Office, GAO-02-280R, *Prescription Drugs: Prices Available Through Discount Cards and From Other Sources (2001)*. This report states that prescription prices for certain medications were cheaper online than at traditional drugstores.

² Id.

³ Ludmila Clifton, *Internet Drug Sales: Is it Time to Welcome "Big Brother" Into Your Medicine Cabinet*, 20 J. Contemp. Health L. & Policy 541, 544 (2004).

With the rising health care costs many health care providers, such as HMOs, frequently change the doctors in their programs.⁴ The frequent changing of doctors provides for an unstable doctor-patient relationship. Patients no longer have adequate time to become comfortable with their doctors, thereby diminishing the importance of the relationship.⁵ In addition, rising health care costs have caused many doctors to decrease the average time spent with patients so that they can see more patients on an average day.⁶ The combination of these circumstances has caused patients to minimize the importance of an in-office consultation or examination by physicians.

Changes in FDA regulations have also significantly contributed to the rising usage of online pharmacies. In 1985, the FDA lifted the ban on Direct-to-Consumer advertising, although it maintained its policy on discouraging such marketing.⁷ Later, in 1999, the FDA further exposed consumers to pharmaceutical advertisements by allowing broadcast advertising, yet still required manufacturers to fully disclose all the risks and side effects of the advertised drugs.⁸ The increased exposure to pharmaceutical advertising through all modes of communication (t.v., radio, magazines, web, etc.) coupled with less face –to- face consultations has given patients a false sense of empowerment. Consumers have begun to “self-diagnose” themselves and use online pharmacies to order prescriptions accordingly.

In late July 2003, Congress voted to allow Americans to import FDA-approved prescription drugs from Canada and much of Europe- a move that will probably increase

⁴ Id. Citing, Ronald L. Scott, *Cybermedicine and Virtual Pharmacies*, 103 W. VA L. REV. 407, 411 (2001).

⁵ Id.

⁶ Id.

⁷ Id. Citing, Andrew Somora, *Direct-to-Consumer Advertising: Are Consumers Being Informed*, 8 KAN. J.L. & PUB Policy 205, 206 (1999).

⁸ April L. Foreman, *Web of Manipulation: The Learned Intermediary Doctrine and Direct-to-Consumer Advertising on the World Wide Web*, 35 J. MARSHALL L. REV. 97, 100-101, (2001).

Web sales exponentially if it ever becomes law. Americans purchased approximately \$350-650 million worth of drugs from Canada over a 12-month period in 2002-2003, according to IMS Consulting, which provides research on the pharmaceuticals industry.⁹ It is easily suspected that such a change in law would increase the usage of on-line pharmacies. In this instance, websites based out of Canada and Europe will likely experience an influx of sales from American consumers.¹⁰

Evidently there are many time and cost incentives to this practice, especially for Americans without health insurance and prescription drug coverage.¹¹ Notwithstanding these incentives, online pharmacies and their loose criteria for filling prescriptions are placing consumers at extreme health risks and promoting further drug abuse by prescription drug addicts and providing easy access to children.¹²

B. Advantages of Online Pharmacies

The foremost advantage that online pharmacies provide is lower prices. The lower prices are facilitated through the absence of many operating costs associated with traditional brick and mortar sites, which include building costs, property taxes, and labor and employee training costs. Further, as more Americans use the Internet, the competition among online pharmacies for market share increases, which can create price wars among competitors in an effort to attract consumers.¹³ “Online pharmacies also provide consumers the ability to comparison shop for drug price and availability. Also,

⁹ Stacey Lu, Promise or Peril, Consumer Reports Magazine, September 29, 2003.

¹⁰ Id.

¹¹ Id.

¹² Id.

¹³ Supra at Note 1.

sites whose operations are situated in foreign nations operate from different regulations and pricing structures.”¹⁴ This is advantageous to consumers because these less regulated nations are able to offer cheaper prices in comparison to traditional American pharmacies.¹⁵

Additionally, online pharmacies are extremely convenient. For example, elderly consumers who do not drive or who do not live in close proximity to a pharmacy can have medication delivered to their home.¹⁶ Ordering on the web is also time-efficient in that consumers can save their medical and pharmacological profiles online. This feature permits the ease of refilling prescriptions in a matter of minutes, which can be delivered directly to the patient’s home or be picked up from a local site.¹⁷

Lastly, using online pharmacies affords consumers with more privacy than the traditional doctor or pharmacy visit.¹⁸ Many websites allow consumers to participate in a virtual consultation where they can input their respective symptoms and conditions and receive a diagnosis with accompanying patient information.¹⁹ Sites such as these are therefore popular because of their high degree of privacy since patients can forego face-to-face examinations or visits to the pharmacist that can be embarrassing and uncomfortable.²⁰

¹⁴ Kristin Yoo, *Self-Prescribing Medication: Regulating Prescription Drug Sales On the Internet*, 20 J. Marshall J. Computer & Info. L. 57, 59, (2001).

¹⁵ *Id.*

¹⁶ At a recent congressional hearing, a senior citizen testified that as a cancer survivor he is required to take medication on a daily basis. Constantly traveling back and forth from a conventional pharmacy had become very difficult. By using an online pharmacy, medication could be shipped overnight to his front door, saving time and aggravation.

¹⁷ *Id.*

¹⁸ *Supra* Note 12.

¹⁹ *Id.*

²⁰ *Id.* at 60.

C. Disadvantages of Online Pharmacies

In many respects, the benefits that online pharmacies offer are outweighed by the existing and potential damages they can cause to an individual's health and to society as a whole. The ability to access prescription drugs without a confirmed face- to- face physician consultation creates a large risk of misdiagnosis which, in turn, results in the wrong prescription being dispensed.²¹ Online pharmacies also provide a relatively effortless way for drug abusers and addicts to acquire prescription drugs. Furthermore, many web sites are breaking federal and state consumer protection laws by representing that certified doctors are offering their medical opinions and prescribing drugs when, in reality, a computer database is deciding the appropriate drug or remedy.²²

The biggest risk that online pharmacies pose is to the patient's health. Many sites offer very limited consultations and require the patient to answer only a few questions before prescribing a medication.²³ The Subcommittee on Commerce of the House Committee on Oversight & Investigations deemed this type of practice by sites as failing to meet the required patient-physical relationship prior to prescribing a FDA regulated drug.²⁴ This position is solidified by the American Medical Association (AMA), the National Association of Boards of Pharmacy (NABP) and the Department of Justice (DOJ) which state that the questionnaires that substitute for actual physical examinations may be breaking the law.²⁵

²¹ Id.

²² Id.

²³See, Drugstores on the Net: The Benefits and Risks of Online Pharmacies, Before the Subcomm. on Commerce of the House Comm. On Oversight & Investigations, 106th Cong. 4 (1999) (statement of Rep. Upton)

²⁴ Id.

²⁵ Id.

Further, consumers face an increased health risk when they purchase prescription drugs from online pharmacies based in foreign countries. Many websites market products which are classified as vitamins, herbs, or dietary supplements in the U.S., as legitimate prescription drugs. In other instances, drugs that can only be purchased with a prescription in the U.S, such as codeine, can be purchased without one through a foreign online pharmacy.²⁶ “Appearance, dosages and even product names can differ from country to country.”²⁷

Another major issue with the increased use of online pharmacies is its simplicity of ordering prescription drugs thereby permitting children and drug abusers to acquire non- prescribed medication easily. The National Institute on Drug Abuse, reported that an estimated 9 million people aged 12 and older used prescription drugs for non-medical reasons in 1999.²⁸ One government report indicates that an increasing number of young adults and teenagers are abusing prescription drugs.²⁹ CBS News reported, “In 2001, nearly 3 million young people, age 12 to 17, reported that they had used prescription drugs for non-medical reasons at least once, the government said. The number of new users has been climbing since the mid-1980s.”³⁰

²⁶ Supra Note 7.

Also note that a study published in October 2002 by the American Journal of Medicine found 59 Web sites trying to sell Cipro the month after the October 4, 2001, outbreak. Twenty-three Cipro-selling sites sprung up in two weeks, none requiring a prescription.

²⁷ Id.

²⁸ Rogue Sites Deal Dangerous RX, see:

<http://www.cbsnews.com/stories/2003/01/16/health/main536752.shtml> , Oct 20, 2003

²⁹ Id.

³⁰ Id. This story also notes that: “ In 2001, there were about 90,000 visits for abuse of these narcotics, a 117 percent rise over 1994, according to data from the Drug Abuse Warning Network. The largest increases were found in abuse of Oxycodone, methadone and morphine. A report based on the National Household Survey of Drug Abuse, which consisted of annual survey that included 69,000 people in 2001. That includes more than 45,000 people age 12 to 25. It found that in 2001, 36 million Americans — 16 percent of all people age 12 and up — had used prescription drugs non-medically at least once in their lives. That

Many of the online pharmacies on the web are breaking state and federal consumer protection laws by essentially confusing consumers into believing that it is perfectly legal to order prescription drugs without the consent of a licensed physician. Additionally, websites that are offering vitamins and dietary supplements as prescribed drugs are breaking consumer protection laws such as Section 5(a) of the FTC Act, which provides that "unfair or deceptive acts or practices in or affecting commerce are declared unlawful".³¹ Illegitimate websites that portray themselves as having licensed physicians conducting virtual consultations are also in violation of Section 5(a) and FDA regulations.

D. Types of Online Pharmacies

The online pharmacy industry can be categorized into three major classifications. The first and most legitimate type of online pharmacy is the one that operates similarly to a traditional "brick and mortar" pharmacy.³² These types of online pharmacies most resemble the long existing mail order pharmacies. These pharmacies follow FDA and state regulations by employing state-licensed pharmacists and they also require the consumer to obtain a prescription that is written by a licensed physician after an examination or consultation. Subsequently, the consumer has the option of having the physician phone, fax, or mail the respective prescription to the online pharmacy.³³ After the pharmacy has received the prescription, the standard practice is to verify it with the physician and thereafter it will decide to dispense the prescribed drugs.³⁴

includes people who took a drug that had not been prescribed for them and those who took drugs only for the experience or feeling they caused."

³¹ See: 15 U.S.C. Sec. 45(a)(1).

³² Supra Note 13, at 62.

³³ Id.

³⁴ Id.

The second type of online pharmacy is more appealing to consumers because it offers consumers both physician services and pharmacist services. Initially, the consumer will fill out a medical questionnaire which provides the online doctor with the patient's health profile, current medications, and a medical history.³⁵ Based on this information the online doctor will determine the patient's medical condition and prescribe a medication accordingly. Following the diagnosis, the patient can purchase the prescribed medication from the website. Some websites may charge for both the consultation and for the medication while others may solely charge for the medication.³⁶ These types of pharmacies not only prove to be more convenient but also provide a higher degree of privacy appreciated by many consumers.³⁷

The final type of online pharmacy is classified as a "rogue" pharmacy. Federal and state lawmakers continue the battle to shut down these websites because they pose the highest risk to a patient's health.³⁸ Lawmakers are extremely concerned with rogue pharmacies because they essentially allow consumers to purchase prescription drugs without a physician's consultation and a valid prescription.³⁹ Consumers simply have to log on to the site and fill out an order form requesting their choice of prescription drugs and quantity. These sites are popular for obtaining "lifestyle" drugs such as Viagra, whose prescriptions many consumers are hesitant and embarrassed to solicit from their physicians.⁴⁰

³⁵ Id. Citing Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. Med. & Ethics 98, 98 (2000).

³⁶ Id. at 99.

³⁷ Sean P. Harvey, *Pharmaceutical Dispensing in the "Wild West": Advancing Health Care and Protecting Consumers through the Regulation of Online Pharmacies*, 42 Wm. & Mary L. Rev. 575, (2000).

³⁸ Id.

³⁹ Id.

⁴⁰ Bernard S. Bloom & Ronald C. Iannacone, *Internet Availability of Prescription Pharmaceuticals to the Public*, 131 *Annals of Internal Med.* 830, 832 (1999).

Rogue pharmacies that are located in a foreign country, in comparison to virtual domestic pharmacies, pose an even greater threat to consumers. “FDA authorities consider foreign rogue pharmacies to be the most dangerous because of their willingness to sell potentially dangerous controlled substance to virtually anyone, which include drugs that are unapproved for medical use in the U.S.”⁴¹ Since many of these websites are maintained under fictitious names and are based out of foreign countries, U.S authorities have no means of regulating them or monitoring their activities.

Rogue websites create numerous perils to consumers because they allow consumers to self-diagnose and access harmful medication based on their own non-medical opinion. Additionally, these websites allow prescription drug abusers and children to easily acquire their drug of choice.⁴²

III. Current Federal and State Regulation

Both state and federal governments are taking very precautionary steps in enforcing and enacting new legislation that does not hinder the benefits provided by online pharmacies, but which does limit the health risks that they pose to consumers. The Federal government continues to attempt passing legislation that will provide the States with the authority to seek injunctive relief beyond their territorial borders. Additionally, the Federal government strives to establish a cohesive system for regulating online pharmacies as a replacement of the current system where enforcement power is spread among various departments and agencies.

⁴¹ Id. at 576.

⁴² One article explained that “one must only go to Google, type in “no prescription codeine” and hundreds of sites appear. Fifty-three out of the first 100 offer opiates without a prescription, said Robert Forman, PhD, a researcher at the Treatment Research Institute, University of Pennsylvania, Philadelphia” see: [amednews.com, http://www.ama-assn.org/amednews/2003/12/22/hlsa1222.htm](http://www.ama-assn.org/amednews/2003/12/22/hlsa1222.htm)

A. Federal Agencies

The Federal government governs online pharmacies using the many different regulations promulgated by various federal agencies. Among the various agencies that have enacted legislation to regulate the online pharmacy industry is the FDA. The FDA specifically derives its power to regulate the industry of prescription drugs by means of the Food, Drug and Cosmetic Act (FDCA).⁴³ This Act excludes the “introduction or delivery for introduction into commerce of any food, drug, device or cosmetic that is adulterated or misbranded.”⁴⁴ In this instance, medication that is dispensed without a valid prescription by a licensed physician is considered ‘misbranded.’⁴⁵ The FDCA also gives the FDA the power to police interstate shipments, and importation of unapproved drugs.⁴⁶

To address the problem of online pharmacies in foreign countries, the FDA has begun to send “cyber letters” to foreign pharmacies that it suspects are selling illegal prescription drugs to Americans.⁴⁷ The cyber letter is only a warning letter that puts the pharmacy on notice that it may be violating U.S. laws, and that U.S. customs officers may refuse entry of packages delivered from their site into the country.⁴⁸ In addition, the FDA sends cyber letters to the rogue pharmacy’s respective government agency reiterating the same notification.⁴⁹ Many critics assert that cyber letters have no real impact on regulating foreign online pharmacies because they are mere warning letters with no consequence for noncompliance. The FDA has no authority over foreign

⁴³ Supra Note 1 at 555.

⁴⁴ Id., citing 21. U.S.C. § 301 (2000).

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Supra at Note 13., 74

⁴⁸ Id.

⁴⁹ Id.

websites to demand their compliance with U.S. regulations, nor does it have any other mechanisms to stop these websites from existing.⁵⁰

In addition to the FDA's regulations, the Federal Trade Commission (FTC) is also vested with the power to regulate the online pharmacy industry. The FTC's main purpose is to regulate and promote competition while protecting the public from "*unfair and deceptive acts and practices in advertising and marketing of goods and services.*"⁵¹ The FTC derives this power from the Federal Trade Commission Act passed in 1914. The FTC has yet to promulgate a specific act addressing online pharmacies.⁵² Although, in 1999, the FTC did introduce a new initiative called "Operation Cure All" which was aimed "to stop bogus Internet claims for products and treatments touted as cures for various diseases. Over two years, the FTC identified about 800 sites and numerous Usenet newsgroups containing questionable promotions."⁵³

Congress has also provided the Drug Enforcement Agency (DEA) with the power and jurisdiction to regulate another aspect of the online pharmacy industry. The DEA via The Controlled Substance Act (CSA) requires that "all persons who manufacture, distribute, dispense, export, or import a controlled substance in the United States register with DEA unless specifically exempted under another law or regulation."⁵⁴ Further, the CSA specifically prohibits the dispensing of controlled substances without a valid prescription.⁵⁵ The DEA derives further power to regulate online pharmacies from the Comprehensive Drug Abuse Prevention and Control Act of 1970. This Act regulates the

⁵⁰ Id at 75.

⁵¹ 15 U.S.C. §§ 41-51

⁵² Id.

⁵³ John Henkel, *Buying Drugs Online: It's Convenient and Private, but beware of 'Rogue Sites,'* see: http://www.fda.gov/fdac/features/2000/100_online.html

⁵⁴ The Controlled Substances Act, 21 U.S.C. §812.

⁵⁵ Id.

manufacturing and distribution of narcotics and chemicals used in the production of controlled substances.⁵⁶

Recently, the DEA has teamed up with the FDA and organized a specific task force, called Operation Graylord, to address the problem of rogue pharmacies. This taskforce has been very aggressive in pursuing rogue pharmacies and those that continuously order from such sites.⁵⁷ Elizabeth Willis of the DEA commented, "If a prescription is written by a doctor based solely on information from an online questionnaire, it's not valid, so the distribution is illegal."⁵⁸ Appropriately, the task force will aim to target rogue pharmacies in the U.S.⁵⁹

This current structure allows the federal government to be very flexible in the type of claim it wants to bring against online pharmacies, while also allowing it to hold online pharmacies accountable at a variety of roles and levels. On the contrary, the absence of a uniform body of regulation provides no formal notice of regulations and laws to online pharmacies, thereby in many circumstances providing them with room to escape liability.

B. Federal Legislation

Lawmakers and industry participants are becoming aware of the need for a cohesive system of regulation on the federal level. Although the need has been identified, there is still a lack of consensus on the means to the end. The disagreement stems from the conflicting objectives and agendas among lawmakers, drug companies,

⁵⁶ The Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. § 801

⁵⁷ FDA and DEA Team-Up Against Online Drug Sales, see: <http://headaches.about.com/cs/beforeyoubuy/a/gran lord.htm>

⁵⁸ Id.

⁵⁹ Id.

online pharmacies, and consumers.⁶⁰ Even in the midst of disagreement, Congress has designed a few legislative proposals which are awaiting enactment. The most recent major proposal is the Internet Pharmacy Consumer Protection Act (herein the “IPCPA” or the “Act”).⁶¹

The IPCPA amends the FDCA by explicitly requiring online prescription providers to disclose the following information: name, address, principal place of business, and telephone number of the dispenser; disclosure of each state in which the person is authorized by law to prescribe the prescription drugs; and name of each individual who serves as a pharmacist for the site and each state that she is authorized to dispense prescription drugs.⁶²

Furthermore, the Act would require websites that provide any medical consultation to disclose the name of each individual who provides such consultation and each state that he or she is licensed to provide such services.⁶³ The Act also requires that an ‘appropriate medical relationship’ exists between the patient and physician.⁶⁴

The crux of the act lies in the power and authority that it grants to the States. Under the IPCPA, state Attorney Generals can bring civil actions in United States Federal District Court against any website on behalf of its residents for violations.⁶⁵ State AGs can seek a variety of remedies including nationwide injunctive relief, which is of paramount importance since it allows them to stop online pharmacies from selling drugs

⁶⁰ Supra Note 1 at 563.

⁶¹ Id.

⁶² Id at 564.

⁶³ Id. Citing Internet Pharmacy Consumer Protection Act, H.R. 3880, 108th Cong. (2004)

⁶⁴ Id. The Act defines ‘appropriate medical relationship’ consisting of at least one in-person medical evaluation by a practioner and a valid prescription.

⁶⁵ Id. at 567.

to not only their state's residents but also the 49 other states.⁶⁶ Other remedies include damages, restitution, and attorney fees.⁶⁷

The IPCPA attempts to reconcile the overlapping of federal and state laws, by delineating explicit regulatory powers to the FDA, and prosecuting and litigating powers to the States. Proponents of the Act assert that it protects consumers by requiring online pharmacies to disclose all relevant and necessary information, and that the consumer has obtained a valid prescription through at least one face-to-face consultation with a licensed physician.⁶⁸ Advocates of the Act find it a success because it “strikes a balance between the federal and state governments by assigning the federal government responsibility to secure broad consumer protection with the power to enforce it, while also preserving an enforcement role for the states.”⁶⁹

In addition to the IPCPA, the Congress has proposed the Prescription Drug Abuse Elimination Act of 2004, with the purpose of limiting drug abuse on the Internet. This Act proposes a state database that would monitor prescription drugs bought from the Internet by gathering such information as: the name and address of the buyer, the type of drug ordered, the quantity, date of prescription, the number of refills, and the expected duration of each prescription.⁷⁰ Each state would have its own respective database and be required to share the information with licensed physicians and other state and federal law enforcement agencies.⁷¹

⁶⁶ Id.

⁶⁷ Id.

⁶⁸ Id.

⁶⁹ Id.

⁷⁰ Id. Citing Prescription Drug Abuse Elimination Act of 2004, H.R. 3870. 108th Congress (2004).

⁷¹ Supra Note 1 at 567.

Critics of this Drug Abuse Act find that the goal of the proposal is legitimate, although the means are not proportional. They raise issues concerning privacy and argue that requiring a database would be thrusting an undue administrative burden upon the States.⁷² Additionally, the legislation is too narrowly tailored towards drug abusers and not consumers as a whole.⁷³

C. State Legislation

States have traditionally regulated pharmacists, physicians and the operation of pharmacies and have the resources for licensing and disciplining health care professionals on a timely basis. The federal government does not have these resources. Federal proposals that would interfere with the states' traditional role in these areas would be of notable concern.⁷⁴

State legislatures have been far more aggressive in regulating online pharmacies. Currently many state legislatures have begun to enact specific statutes aimed at curbing the efforts of online pharmacies. In 1999, Indiana, Illinois and Virginia lawmakers enacted laws related to on-line pharmacies.⁷⁵ The Illinois legislature enacted a law that amended existing legislation requiring its respective state pharmacy department to research and adopt regulations accordingly as a means of regulating online pharmacies.⁷⁶

⁷² Id.

⁷³ Id.

⁷⁴ See the National Conference of State Legislatures website at: <http://www.ncsl.org/statefed/health/olpharmib.htm>.

⁷⁵ Id.

⁷⁶ Id.

Along a similar path, the Virginia legislature adopted a resolution requiring its Board of Medicine and Board of Pharmacy to conduct a study of online pharmacies.⁷⁷ Indiana is more progressive because they require that an on-line pharmacy conducting business in Indiana must comply with the licensure laws of the state in which the on-line pharmacy is domiciled.⁷⁸ Other states, including California and New York have enacted similar laws.⁷⁹

Many other states have enacted even more comprehensive regulations for online pharmacies. On May 26, 2000, New Hampshire officially required mail-order pharmacies, which includes online pharmacies, to register for a permit with the state pharmacy board. A permit is granted only when a website meets certain specified requirements.⁸⁰

Many state legislatures have also specified that it is a violation of state law to prescribe drugs without first exercising a good faith examination. California has enacted a law that makes it illegal to prescribe patients online without a good faith prior medical examination. Along with California, Kansas, New York, Alabama, Ohio, Oklahoma, Maryland, Texas, Oregon, Michigan, Delaware, and Vermont have also managed to enact similar statutes, thereby effectively reducing many of the potential disadvantages and abuses associated with the online pharmacy industry.⁸¹

⁷⁷ Id.

⁷⁸ Id.

⁷⁹ Sara E. Zeman, “*Regulation of Online Pharmacies: A Case for Cooperative Federalism*,” 10 *Annals Health L.* 105.

California requires those practicing medicine from California into another state or country to first have met the other jurisdictions requirements for practicing medicine.

New York law requires online pharmacies to comply with New York Licensing requirements for conducting business in New York.

⁸⁰ Id.

⁸¹ Id.

The increasing trend of state legislatures passing statutes to influence the online pharmacy shows promise. More and more states are becoming aware of the problems associated with online pharmacies. But having individual state legislation governing the online industry may not be the answer. Having different rules and regulations in every state may burden an online pharmacy with extensive administrative and compliance costs; consequently, the extra costs will be reflected in the drug prices. Therefore, current and future state legislation addressing online pharmacies should be broadly drafted to protect consumers, while still preserving the main benefits associated with virtual drug marketplace.

D. Prosecutions by State Attorneys General

While many state legislatures have been slow and unresponsive to the potential damages that online pharmacies may have on their residents, state Attorneys General (AG) have been quick to realize the threat and actual damage that online pharmacies cause. Consequently, many state AGs have brought legal action against online pharmacies. The AGs bring their cases all based on similar statutes and legal theories.⁸² AGs derive their power from state statutes that empower them to bring cases on behalf of the state citizens. The AG is charged with the responsibility to handle legal affairs of state agencies and the ability to be involved in any legal matter affecting the state interest.⁸³

Attorneys General from Illinois, Michigan, Missouri, Kansas, New Jersey, and a handful of other states have brought cases against online pharmacies with similar claims.

⁸² Id.

⁸³ Id. Citing: Luther C. McKinney & Dewey J. Caton, *What to Do When the Attorney General Calls: State Regulation of National Advertising*, 3 Depaul Bus. L.J. 119, 121-25 (1991).

Initially, states began bringing cases of this nature in 1999. The Missouri Attorney General, Jeremiah Nixon, brought one of the first cases against an online pharmacy.⁸⁴ The AG claimed that, pillbox.com, a Texas-based online pharmacy, violated state law by not meeting Missouri's licensing requirement to dispense prescription drugs to Missouri residents. Nixon also asserted violations of consumer protection laws by the online pharmacy since it represented that it was a licensed pharmacy with licensed pharmacists and physicians.⁸⁵ In the end, the AG was able to get \$15,000 in penalties imposed on those involved with the pharmacy and a permanent injunction that would disallow any sales to Missouri residents.⁸⁶

Shortly after the Missouri case, the Illinois AG, Jim Ryan, placed suit against four online pharmacies in October 1999.⁸⁷ Following along the same guidelines of the Missouri case, Ryan asserted violations of the state's medical and pharmacy requirements and violations of the state's consumer fraud law.⁸⁸ Ryan claimed that the online pharmacies were in violation because they conducted business by having doctors who were not licensed in Illinois, issuing prescriptions to Illinois residents, followed by out of state licensed pharmacists dispensing the prescriptions.⁸⁹ The main concern in this case was that the pharmacies prescribed the controlled drugs without an appropriate doctor-patient relationship.⁹⁰

Later that same year, in December 1999, and March 2000, Michigan and New Jersey Attorneys General respectively, brought suit against online pharmacies practicing

⁸⁴ Supra Note 71 at 124.

⁸⁵ Id.

⁸⁶ Id.

⁸⁷ Id.

⁸⁸ Id.

⁸⁹ Id. at 126.

⁹⁰ Id.

in their states.⁹¹ The complaints alleged violations similar to those in Missouri and Illinois, and sought similar remedies. Both cases were successful with the former settling before trial with an agreement to discontinue sales of prescription drugs to residents of Michigan.⁹²

1. NAAG and the Concept of Multi-state Litigation

The National Association of Attorneys General (NAAG) is an organization comprised of federal, state, and regional attorneys general that work together to “facilitate interaction among Attorneys General, thereby enhancing their performance...to respond effectively to emerging state and federal issues.”⁹³ On May 25, 2000, in her testimony before the United States House of Representatives, Kansas AG, Carla J. Stovall explained that “we (NAAG) are not interested in shutting down websites operating in compliance with all licensing and registration laws and regulations in the states to where they dispense the medication.”⁹⁴ Stovall further explained, “all of the defendant pharmacies tried by the states had one thing in common—they did not require a valid physician-patient relationship to prescribe and to dispense prescription drug-only drugs.”⁹⁵

NAAG has established the Online Pharmacy Working Group, (herein, the “Group”) a formal coordinated effort among the states to contest the harms of online pharmacies.⁹⁶ The Group has established simple effective modes of exchanging information between states, so that each State licensing entity or Attorney General’s

⁹¹ Id.

⁹² Id.

⁹³ See: *Kansas Attorney General Carla Stovall Testifies On Illegal Online Pharmacies, State-Federal Cooperation to Protect Consumer*, http://www.naag.org/legislation/stovall_online_pharm.php.

⁹⁴ Id.

⁹⁵ Id.

⁹⁶ Id.

office can use the information for its own investigation.⁹⁷ States began to pattern their cases against online pharmacies along the same underlying statutes, theories, and public policy concerns, as evidenced by their respective cases. The scenario represents aspects of the concept of “Multi-State Litigation”, where state Attorneys General attempt to regulate a national industry lacking appropriate federal agency legislation, through a cooperative effort using litigation tools in state courts.⁹⁸

Although, many AGs have proactively begun to bring actions against online pharmacies, it is still indeterminable that all the states will follow. Many state legislatures have yet to enact statutes that address the issues of online pharmacies, thereby restricting the authority of their state AG to bring a claim for direct violations. Even though almost all AGs could bring a strong claim against online pharmacies under their respective state consumer laws, many state AG offices lack the resources, and others opt to not face the criticism that NAAG faces in similar multi-state litigation. Critics argue that Attorneys General are overstepping their boundaries by trying to regulate business practices through litigation because it would be more efficiently handled and tailored by the state legislatures.

Due to the lack of federal legislation and limited jurisdiction and enforcement authority, NAAG, in its March 22-24, 2000 Meeting, adopted a resolution asking Congress to pass legislation that would take a “joint enforcement approach that complements and enhances, rather than preempts, state consumer protection enforcement,

⁹⁷ Id.

⁹⁸ James Tierney, lectures in Multi-State Litigation class, Northeastern University School of Law, Spring 2005.

allowing states officials the option to determine which law and relief is appropriate.”⁹⁹

Additionally, NAAG asked for legislation that would grant authority to seek nationwide injunctive relief in Federal U.S. District Court.¹⁰⁰ This remedy and others are reflected in the IPCPA, which still has not been passed by Congress.¹⁰¹

2. Private Sector Initiatives

To confront and tackle some of the harsh government and consumer criticism that online pharmacies are facing, some private sector associations, such as the National Associated of Boards of Pharmacy (NABP), have decided to impose self-regulation measures. The NABP is a professional organization that consists of the Board of Pharmacy from all 50 states.¹⁰² In response to the public and government concern of the harms of purchasing from online pharmacies, NABP implemented the Verified Internet Pharmacy Practice Sites (VIPPS) program in the spring of 1999.¹⁰³ A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria which VIPPS-certified pharmacies follow.¹⁰⁴

To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.¹⁰⁵ Complying sites will display a seal indicating that it meets the established standards regarding patient privacy, authenticity of prescription orders, and quality assurance.¹⁰⁶

⁹⁹ See: NAAG Resolution: *In Support of Legislation Encouraging Cooperative Federalism to Protect Consumers on the Internet*, http://www.naag.org/legislation/NAAG_resolution.pdf

¹⁰⁰ Id.

¹⁰¹ Id.

¹⁰² The National Board of Pharmacy website, see: <http://www.nabp.net/>

¹⁰³ Id.

¹⁰⁴ Id.

¹⁰⁵ Id.

¹⁰⁶ Id.

Although in theory this program sounds ideal, in practice it lacks enforcement. The VIPPS program is entirely voluntary, and NABP has no authority to legally reprimand a pharmacy violating its certification requirements.

There has been no considerable following by other national professional organizations to implement programs that combat the dangers of the online pharmacy industry. Many prominent professional associations continue to neglect the problems caused by online pharmacies. For example, the American Medical Association, (AMA) which is a professional association comprised of physicians across the U.S., and the Committee on Professional Conduct and Ethics-a subdivision of the Federations of State Medical Boards, have issued reports and considered implementing policies; however, they have failed to initiate any type of formalized program to address the major health concerns of buying prescription drugs from online pharmacies.¹⁰⁷

IV. Conclusion

The rapid growth of E-commerce continues to present challenges for federal and state governments. Thus far the existing federal and state laws have experienced limited success in curbing the sell of prescription drugs on the Internet. The federal government continues to lag in passing specific legislation aimed at the online pharmacy industry. Although various federal agencies have applicable consumer protection laws, they lack the capabilities to effectively handle the increasing number of illegitimate pharmacies. State attorneys general have been effective in bringing suits in their respective states, but

¹⁰⁷ See: AMA's Website: <http://www.ama-assn.org/ama/pub/category/1810.html> and www.fsmb.org

their lack of jurisdiction allows national online pharmacies to continue to sell their prescription drugs to other states.

The most effective and logical solution that has been proposed has been the IPCPA. It draws an ideal balance between the federal and state governments. The act allows the federal government to regulate and promote consumer awareness about the online industry by passing the appropriate legislation and awareness programs or delegating the authority to an agency such as the FDA to promulgate regulations over the industry. By allocating prosecuting powers to the states and their Attorney General, the IPCPA places the states in an integral role in combating illegitimate online pharmacies. This will be more effective because the states will be better equipped to investigate and prosecute the states than the under budgeted FDA or FTC.

The objective of eliminating illegitimate pharmacies will require active cooperation between the federal government and the states. Legislation must be carefully crafted to regulate the Internet prescription sales, thereby reducing the harm to consumers while still allowing them to take advantage of the benefits of online pharmacies